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GUIDELINES REGIONAL MEDICAL PROGRAMS

HEART DISEASE, CANCER, STROKE,
AND RELATED DISEASES



U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE Public Health Service

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Each grant for construction is subject to the condition that the grantee shall comply with the requirements of the Executive Order 11246, 30 F. R. 12319 and the applicable rules, regulations, and procedures as prescribed by the Secretary of Labor.

GUIDELINES

REGIONAL
MEDICAL PROGRAMS

Division of Regional Medical Programs
National Institutes of Health
Bethesda, Maryland 20014
U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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GUIDELINES

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CONTENTS AND USE OF THIS GUIDE

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This Guide is for use in applying for support under Title IX of the Public Health Service Act (Public Law 89-239), which authorizes grants to assist in planning, establishing, and operating Regional Medical Programs to combat Heart Disease, Cancer, Stroke, and related diseases. It is therefore intended to be used for both planning and operational grant applications.

The contents of this Guide include the history and purposes, composition, policies and definitions and general information regarding the preparation and review of applications for a Regional Medical Program.

The provisions of this Guide are intended to carry out the purposes and objectives of the authorizing legislation, consistent with overall policies of the Department of Health, Education, and Welfare and sound fiscal procedures. These provisions must be interpreted in light of the basic objectives of the program, and the clear intent of the Congress to stimulate initiative and innovation at the regional level in planning and implementing regional programs that are fitted to the needs and resources of the region.

If the applicant believes there is a conflict between the provisions of the Guide and the effective implementation of the proposed program in his region, he is encouraged to consult with the staff of the Division of Regional Medical Programs. This is a new program in an exploratory phase. It is expected that policies and procedures will

evolve with time as both the applicant and the Division learn from actual planning and operational experience. As with all statements of policy and procedure, the Guide attempts to strike a balance among desirable and necessary procedures. The Division encourages diversity and innovation in the development of the Regional Medical Program. But this flexibility of approach must take place within the boundaries of the legislative authority, applicable general policies, and the necessary accountability for public funds.

I. HISTORY AND PURPOSES OF REGIONAL MEDICAL PROGRAMS

I. HISTORY AND PURPOSES OF REGIONAL MEDICAL PROGRAMS

The impetus for the Regional Medical Programs was contained in the President's 1964 Special Health Message to Congress when he proposed to establish a Commission on Heart Disease, Cancer, and Stroke "to recommend steps to reduce the incidence of these diseases through new knowledge and more complete utilization of the medical knowledge we already have." In March 1964, a Commission of distinguished physicians, scientists, and informed citizens was appointed to accomplish this task. The Commission collected information from agencies, groups, and institutions concerned with these diseases through letters, staff visits, surveys, etc., held hearings at which expert witnesses from the widest possible range of interests, both public and private, presented their views, and submitted a report which included the following points:

"Our Nation's resources for health are relatively untapped. The rising tide of biomedical research has already doubled our store of knowledge about heart disease, cancer and stroke...."

"Yet for every breakthrough, there must be follow-through. Many of our scientific triumphs have been hollow victories for most of the people who could benefit from them."

The Commission presented 35 recommendations aimed at reducing the toll of these diseases through the development of more effective means of making the latest medical advances available to a greater portion of the population and through the provision of additional opportunities for research. The major recommendations of the Commission are the basis for

the proposed regional medical programs authorized by Public Law 89-239 (hereafter referred to in this text as "The Act". See Exhibit).

The Act is intended to assist our medical institutions and professions in capitalizing on the rapid advances of scientific medicine in the prevention, diagnosis, treatment, and rehabilitation of patients afflicted with heart disease, cancer, stroke or related diseases. To paraphrase the statement of purposes in the Act, these grants are to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutes, hospitals and other medical institutions and agencies for the purpose of affording the medical profession and the medical institutions the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases. Grant funds will support through these cooperative arrangements research, training (including continuing medical education) and related demonstrations of the highest standard of patient care. Through these means the program is also intended to improve generally the health manpower and facilities of the Nation. The Act states that these purposes should be accomplished without interfering with the patterns of professional practice or hospital administration.

The intent of the Act is built upon the following basic premises and assumptions:

1. The program will utilize and build upon existing institutions and manpower resources.
2. The active participation of practicing physicians is essential to the success of a regional medical program.

3. The purposes can best be achieved through initiative, planning, and implementation at the regional level under conditions which encourage innovative approaches and programs specifically designed to deal with the diversity of needs, resources and existing patterns of education and service.

4. Cooperation among all essential elements of the health resources in a region is an essential means of coping with the complexities, specialization, high cost, manpower needs, and educational and training needs which are the by-products of the dynamic advances of medical science. The objectives of the Act will not be achieved by a program which serves the interests of a single category, institution, or organization. A basic aim of the program is to overcome fragmentation and insularity.

5. In order to insure an effective linkage between research advances and improved patient care, it is desirable to establish a continuing relationship among the research and teaching environment of the medical center, the patient care activities involving the community hospital, and practicing physicians. The impact of research advances on the development of high quality patient care has typically been most direct in the university medical centers or other medical centers which combine extensive research teaching and patient care activities. The primary benefits of this interrelationship, however, have often been confined to the medical center itself and affiliated hospitals. A basic premise of the Act is the desirability of extending this productive interrelationship to additional hospitals and to practicing physicians through the establishment of regional cooperative arrangements.

6. The financing of patient care is not the objective of the regional medical programs. The payment of patient care costs is limited to those costs incident to research, training and demonstration activities supported by these grants.

7. It is assumed that the development of the full capabilities of a regional medical program will take a number of years. The purpose of the first three years of legislative authorization is to encourage and assist in the planning and implementation of the first steps toward the establishment of a regional medical program. It is assumed that the development of a plan and the implementation of the initial elements thereof will constitute a learning experience which can be utilized in taking additional steps in the cooperative effort against heart disease, cancer and stroke.

The background against which these assumptions and premises are set includes a number of trends and influences which have been affecting the nature of medical service, education, and research for some years. The opportunities created by the impact of science on modern medicine have already been mentioned. Along with the creation of opportunities, however, the increasing impact of science has changed the nature and shape of modern medicine, raising a number of situations which are very difficult to manage, including increased specialization, increasing complexities and costs of diagnosis and treatment, and the difficulties in transmitting a rapidly expanding body of knowledge. The tremendous growth of knowledge through large scale research efforts is a characteristic of our times, not just in medicine but in most aspects of our society. Wherever this phenomenon is seen, it calls for the development

of new means of coping with steady and dynamic change if the benefits of the knowledge are to be realized.

The forces of change can be viewed as part of a continuum existing over many years, rather than a revolutionary or radical alteration of current patterns. This trend calls for the development of Regional Medical Programs which create an effective environment for continuing adaptation, innovation, and modification. The development of a great medical research effort is the product of a deliberate national policy to stimulate and support the development of new medical knowledge at a rapid rate. The passage of the legislation authorizing Regional Medical Programs represents a corresponding commitment to assist the development of necessary measures to bring the benefits of this new knowledge to the patient in the field of heart disease, cancer, stroke, and related diseases.

The process of medical education in all its aspects has also been undergoing a change under the impact of the growth of knowledge. The development of great medical centers built around education, research, and high-quality patient care has taken place throughout the Nation. The consequence of rapid expansion in the body of medical knowledge is increased specialization, resulting in the prolongation of the educational process. A continuing process of education throughout the career of a physician is therefore of great importance.

The continued evolution of medical education and the growth of the medical centers carries with it increased problems in maintaining an effective linkage between the medical center and the practicing physician. Recent reports have emphasized the need for those concerned

with medical education to assume responsibilities in meeting national needs for improved health care. It has become clearly apparent that the medical center represents an indispensable resource for improving health in its area of influence. In the environment of medical education, new attention is being given to the need to cope effectively with the problems brought about by the developments in modern scientific medicine.

Many medical leaders are stressing that those involved in health care must maintain a continuous relationship to the educational process and that medical schools and hospitals should have an increasing involvement in the process of continued learning. The very forces that have tended to separate the centers of medical knowledge from the practicing physician are creating an ever greater need to bring physicians into continuing contact with the environment of teaching and research.

Another trend is usually described as the regionalization of medical services. There have been numerous regionalization proposals during the past 35 years and efforts have been made to implement various approaches to regionalization. The concept of Regional Medical Programs includes the regional approach to the provision of highly specialized services involved in the diagnosis and treatment of heart disease, cancer, stroke, and related diseases. The legislation provides a very flexible framework for the implementation of a regional approach which is appropriate to the voluntary nature of our medical institutions.

The Regional Medical Programs present the medical interests within a region with an instrument of synthesis that can capitalize on and reinforce the various trends and resources seeking to make more widely available the latest advances in diagnosis and treatment of these

diseases. It is the interaction of these trends at this time, rather than an abstract conceptualization which not only justifies but requires a synthesizing force such as the Regional Medical Programs. The Regional Medical Programs represent a general concept, rather than a specific blueprint. The opportunity is presented to go beyond concept into specific planning and implementation of programs which represent pragmatic steps toward the achievement of the overall goals of the legislation. It is an opportunity to mix creative ideas and specific actions in developing improved means for advancing the health standards of the American people.

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II. COMPOSITION OF A REGIONAL MEDICAL PROGRAM

A. Definition of a Regional Medical Program

The Act defines a regional medical program as a cooperative arrangement among a group of public or private nonprofit institutions or agencies engaged in research, training, diagnosis, and treatment relating to heart disease, cancer, or stroke, and at the option of the applicant, related disease or diseases; but only if such group

1. is situated within a geographic area, composed of any part or parts of any one or more states which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of the Act;
2. consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and
3. has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for carrying out effectively the purposes of this program.

B. The National Advisory Council on Regional Medical Programs

The National Advisory Council on Regional Medical Programs consists of the Surgeon General, who is the chairman, and 12 members, not otherwise in the regular fulltime employ of the United States, who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. In particular, one of the twelve council

members must be outstanding in the field of heart disease, one in cancer, and another in stroke, and two must be practicing physicians. The role of the Council is to advise and assist the Surgeon General in the formulation of policy and regulations regarding the regional medical programs, and to make recommendations to him concerning approval of applications and amounts of grant awards. No grant may be awarded unless it has been recommended for approval by the Council.

C. Categorical Emphasis

The focus of the Regional Medical Programs under the authorizing legislation is on problems of heart disease, cancer, stroke, and related diseases. This rather broad categorical approach must be a consideration in the development of specific program elements under a Regional Medical Program. Heart disease, cancer, and stroke are appropriate targets because of their prevalence as killing and disabling diseases. These diseases present a complex challenge to the research investigator, and the advances which are being made require diagnostic and treatment techniques of great sophistication. Because of the broad scope of heart disease, cancer, and stroke it would be difficult and perhaps detrimental to some types of medical services and educational activities if a rigidly categorical approach were adopted for all relevant program elements. However, the emphasis of the program does require that the program elements be shown to have significance for combating heart disease, cancer, stroke and related diseases.

D. The Region

A region is a geographic area composed of part or parts of one or more states which the Surgeon General determines to be appropriate for the purposes of the program. It should be an economically and socially cohesive area taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; and presence and distribution of educational and health facilities and programs. The region should be functionally coherent; it should follow appropriate existing relationships among institutions and existing patterns of patient referral and continuing education; it should encompass a sufficient population base for effective planning and use of expensive and complex diagnostic and treatment techniques.

E. Cooperative Arrangements Among Resources Within the Region

It is recognized that the full development of a Regional Medical Program, which involves potentially all medical institutions, organizations, and personnel within the region, could take a number of years in many areas. The program emphasizes the development of cooperative arrangements which are effective in making the latest scientific advances in these diseases more widely available. Considerable flexibility is provided for the development of cooperative arrangements that are appropriate to the needs, resources, and patterns of the region. The cooperative arrangements should: 1. Encourage a cooperative attitude and stimulate participation and initiative among

the program elements; 2. Provide for the necessary decision-making framework for the activities conducted under the Regional Medical Program grant; 3. Include administrative and fiscal arrangements, which provide for adequate program coordination and fiscal accountability; 4. Provide for effective administration of central program elements which serve the entire region; 5. Include mechanisms for the evaluation of the effectiveness of the Regional Medical Program, including the acquisition of uniform data for the use in evaluating effectiveness and the means to evaluate specific program elements of the Regional Medical Program; 6. Provide for continual planning and implementation of the further development of the Regional Medical Program.

F. Interregional Cooperation

The definition of a particular region necessarily requires consideration of relationships to adjoining regions. Interregional cooperation is to encouraged, especially in program elements where a uniform approach is desirable. Some examples where interregional cooperation might be beneficial include: 1. Development of standardized criteria for data gathering and analysis; 2. Continuing education programs drawing on the educational resources of more than one region; 3. Referral of patients for highly specialized diagnosis and treatment not available in every region; 4. Program planning and coordination between regions.

Regional boundaries should not cut off existing relationships and patterns and should not operate to the detriment of the objectives of the legislation.

G. The Regional Advisory Group

The Act specifies that an applicant for a planning grant must designate a Regional Advisory Group. The Act also specifies that the Advisory Group must approve an application for an operational grant under Section 904. The Advisory Group must include practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, other health professions, voluntary health agencies, and representatives of other organizations, institutions, and agencies and members of the public familiar with the need for the services provided under the program. It should be broadly representative of the geographic areas and of the social groups who will be served by the Regional Medical Program.

The Regional Advisory Group should provide overall advice and guidance to the grantee in the planning and operational program from the initial steps onward. It should be actively involved in the review and guidance and in the coordinated evaluation of the ongoing planning and operating functions. It should be constituted to encourage cooperation among the institutions, organizations, health personnel, state and local health agencies, and with the state Hill-Burton agencies. It should be concerned with continuing review of the degree of relevance of the planning and operational activities to the objectives of the Regional Medical Program and particularly with the effectiveness of these activities in attaining the objective of improved patient care. Therefore, Advisory Group members should be chosen who will provide a broad background of knowledge, attitudes and experience.

The grantee institution named on the face page of the application is legally and administratively responsible for the conduct of the Regional Medical Program. The Advisory Group does not have direct administrative responsibility for the program, but the clear intent of the Congress was that the Advisory Group would insure that the Regional Medical Program is planned and developed with the continuing advice and assistance of a group which is broadly representative of the health interests of the region. The Advisory Group, therefore, is an inherent element of a Regional Medical Program that helps to accomplish the basic objective of broadly based regional cooperation.

In order to serve these purposes the Advisory Group should operate under established procedures which insure continuity and appropriate independence of function and advice. The Advisory Group is expected to prepare an annual statement giving its evaluation of effectiveness of the regional cooperative arrangements established under the Regional Medical Program.

H. Relation of Regional Medical Programs to Programs of Other Health Agencies

An essential function of Regional Medical Programs is to plan and to provide an environment for coordinating the health resources of the Nation in order to assure the availability of the best of medical care to all persons. It is not the intent of a Regional Medical Program grant to supplant other sources of support for the various program

elements that are related to achieving its purpose. The Regional Medical Program provides an opportunity to introduce program activities which draw upon and effectively link activities already supported, or supportable in the future, through other sources. Current examples of other Federal programs that provide essential inputs into the health resources of the region are: 1. The Bureau of State Services; 2. The Bureau of Medical Services; 3. The National Institutes of Health, particularly the National Heart Institute, National Cancer Institute and National Institute of Neurological Diseases and Blindness; 4. Other constituents of the Department of Health, Education and Welfare, particularly the Social Security Administration, the Office of Education, the Vocational Rehabilitation Administration and the Welfare Administration; and 5. Other government agencies, particularly the Office of Economic Opportunity and the Veterans Administration. The Regional Medical Program grants should concentrate on catalyzing and synthesizing efforts in achieving more effective communication among all of the health related elements in the region.

New sources of possible support for activities related to the Regional Medical Programs should also be considered during both the planning and operational phases. For example, the reimbursement principles for hospitals and other providers of Medicare services should make available to these institutions additional amounts of capital funds, which may contribute to accomplishing the objectives of the

Regional Medical Programs through a cooperative approach to the use of medical resources in the region. •

In order to assure coordination within the Federal Government, the Division of Regional Medical Programs is developing an active exchange of information with these agencies to assure that all pertinent activities are effectively interrelated.

III. POLICIES AND DEFINITIONS

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III. POLICIES AND DEFINITIONS

A. Policies

1. General Responsibilities - The named grantee is obligated, both for itself and cooperating institutions, to administer the grant in accordance with regulations and policies of the Division of Regional Medical Programs. Where a policy is not stated or where the institutional policy is more restrictive than the Regional Medical Program policy, institutional policy prevails.

2. General Assurances - Specific attention is directed to the requirement to honor the assurances provided in the Act.

The recipient of a planning grant must comply with the assurances in Section 903 (b), namely:

a. reasonable assurances that Federal funds awarded to any grantee will be used only for the purposes for which awarded and in accordance with the applicable provisions of the Act and the regulations thereunder,

b. reasonable assurances that the grantee will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement in the accounting for such federal funds,

c. reasonable assurances that the grantee will make such reports in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the

correctness and verification of such reports, and

d. a satisfactory showing that the grantee has designated an advisory group to advise it (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan for the establishment and operation of such regional medical program. The advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives from other organizations, institutions and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the needs for the services provided under the program.

The recipient of an operational grant must comply with the assurances under Section 904 (b), namely:

a. Federal funds awarded to any grantee (1) will be used in accordance with applicable provisions of the Act and the regulations thereunder and (2) will not supplant funds that are otherwise available for establishment or operation of the Regional Medical Program with respect to which this grant is made.

b. The grantee will provide for such fiscal control as fund accounting procedures as are required by the Surgeon General to assure proper disbursement of an accounting for such federal funds.

c. The grantee will make such reports in such form and containing such information as the Surgeon General may from time to time reasonably require and will keep such records and afford such access thereto as the Surgeon General

may find necessary to assure the correctness and verification of such reports, and

d. Any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 USC 276a--276a-5); and the Secretary of Labor shall have with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15FR 3176; 5 USC 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 USC 276c).

3. Surveys or Questionnaires - Surveys or questionnaires arising from and supported by a grant should include a positive statement clearly setting forth that the contents are in no way the responsibility of the Public Health Service.

4. Systems Analysis - This policy statement is to be used by those applicants who desire to incorporate systems analysis methodologies into their applications.

The use of systems analysis methodologies in regional medical programs is encouraged, but only to such an extent as it is considered applicable as an essential integral component of the individual program proposed by the applicant. The applicant should emphasize the development of innovative, adequately formulated studies of realistically restricted problems involving the application of "systems" methodologies rather than submit an application

dominated by general proposals for the utilization of large scale "systems" approaches for the design of a regional medical program.

The Division of Regional Medical Programs will explore through contracts and selective studies the applicability of systems analysis to the planning and implementation of a regional medical program. One approach to the use of systems analysis in current grant applications, within the framework of this policy, is the incorporation of limited numbers of personnel with such analytic skills into the planning process. These personnel may come from university departments or schools of industrial engineering, schools of public health, commercial systems firms, those with experience in program planning and budgeting, and a variety of other sources. It is expected that from such a beginning areas worthy of more detailed activity may well become apparent and qualify for subsequent additional grant support. Applicants are encouraged to direct any questions they may have relative to the use of systems analysis to the Division of Regional Medical Programs.

5. Publications - Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not necessarily represent the views of the Service.

6. Patents and Inventions - The Department of Health, Education and Welfare regulations (945 F.R., Part 6 and 8) provide as a condition that all inventions arising out of the activities assisted by Public Health Service

Grants must be promptly and fully reported in the Public Health Service. Any process, art or method, machine manufacture or improvement thereof, may constitute an invention if it is new and useful and would not have been obvious to a person having skill in the art to which it relates.

In order for the Public Health Service to carry out its responsibility under these patent regulations, it is essential that the Service be advised before awarding Government funds of any commitments or obligations made by the institutions or by the professional personnel to be associated with the activities carried on under the grant which would be in conflict with the inventions agreement. When submitting an application for Regional Medical Programs, the grantee must provide in letter form either:

- a. a statement indicating no previous commitments or obligations have been made, or
- b. a detailed explanation of such commitments or obligations where they do exist.

One such letter will suffice for the named grantee and all cooperating institutions receiving support under the grant. It is the responsibility of the institution named as the grantee on the application to ascertain the facts relating to patents and to report these on behalf of all entities participating in the Regional Medical Program.

In subsequent years an annual invention statement Form PHS-3945 must be filed whether or not an invention has occurred. Where there are no inventions to report, a single form PHS-3945 is all that is required for the institution named on the application as the grantee and for all cooperating institutions. Where there are inventions to report, a separate annual invention statement must be filed for each one. Here again, it is the

responsibility of the grantee to report on behalf of itself and all other entities participating in the Regional Medical Program. The Regional Medical Program grant for the following year will not be issued until the invention statement form PHS 3945 has been received by the Division of Regional Medical Programs.

7. Other Public Health Service Grant Policies - The following Public Health Service grant policies are also applicable to any such activities supported through a regional medical program grant:

a. Clinical Research and Investigation Involving Human Beings -

This policy statement is currently being revised by Public Health Service.

b. Protection of Individual Privacy in Research and Investigation -

(1) Administration of personality tests, inventories or questionnaires. No grant or award of the Public Health Service Extramural Programs in support of research or investigation involving the administration of personality tests, inventories or questionnaires shall be awarded by the Public Health Service unless the application includes a description of the manner in which the rights and welfare of the subjects are assured, that is, how their informed consent is obtained or why this consent is deemed unnecessary or undesirable in the particular instance.

(2) Investigations of persons below the college age level.

No grant or award of Public Health Service Extramural Programs in support of research or investigation involving administration of investigational procedures to persons below the college age level shall be awarded by the Public Health Service unless the application includes a description of the manner in which the rights and responsibilities are respected, that is, how the informed

consent of the parents or guardians is obtained, or why this consent is deemed unnecessary or undesirable in this particular instance.

The professional judgment of the grantee will determine what constitutes respect for the rights and responsibilities of parents or guardians, what constitutes informed consent, and what constitutes a validation for deeming this consent to be unnecessary or undesirable in a particular instance.

c. Animal Care - Each person assigned or appointed to a project receiving any Public Health Service support is required to exercise every precaution to assure proper care and humane treatment of research animals. The booklet, Guide for Laboratory Animals, Facilities and Care (PHS Publication #1024) should be obtained from the Division of Research Grants, Information Office, National Institutes of Health, Bethesda, Maryland, 20014.

The Public Health Service endorses the following guiding principles in the care and use of animals:

(1) Animals should be acquired, retained, and used in compliance with applicable state and local law.

(2) Animals should receive every consideration for their bodily comfort, be kindly treated and properly fed, be kept in sanitary facilities, and be provided with suitable medical care.

(3) With any operation likely to cause greater discomfort than that attending anesthetization, the animal should first be rendered incapable of perceiving pain and should be maintained in that condition until the operation is ended. Exceptions should be made only when anesthesia would defeat the objective of the experiment. In such cases, the anesthesia should

be discontinued only so long as it is absolutely essential for the necessary observations.

(4) If the nature of the study requires survival of the animal, aseptic precautions should be observed during the operation, and care should be taken to minimize discomfort during convalescence comparable to precautions taken in a hospital for human beings. If the animal is severely incapacitated and survival is not a requirement of the experiment, the animal should be sacrificed in a humane manner immediately following final observation.

B. Definitions

1. Approved Program - An approved program is an identified activity approved by the Division of Regional Medical Programs for support for a specific period of time.

2. Budget Period - The budget is the period of time within a program covered by a specific budget, usually 12 months.

3. Clinical Research Center - A Clinical Research Center is an institution (or part of an institution), the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients. The clinical research center may be a part of the medical center or it may be a separate institution.

4. Construction - Construction means alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing

buildings with prior approval (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

5. Grant - A grant is the total amount of direct and indirect costs which is awarded to a grantee for support of an approved program for a specific period of time.

6. Grantee - The grantee is the applicant institution who is named on the face page of the application and who assumes responsibility for the grant.

7. Hospital - The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, out-patient departments (nurses' home facilities), central service facilities operated in connection with hospitals, and other health facilities in which local capability for diagnosis and treatment is supported and augmented by the program established under this Act. It does not include institutions furnishing primarily domiciliary care. Proprietary hospitals may participate in the Regional Medical Program but may not be funded under the Act.

8. Medical Center - Medical Center is a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.

9. Non-Profit - Non-profit as applied to any institution or agency means an institution or agency which is owned and operated by one or more non-profit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

10. Practicing Physician - A practicing physician is any physician

licensed to practice medicine in accordance with applicable state laws.

11. Program Period - The program period is the time for which new or continuing support has been recommended. The initial grants may be for any period up to June 30, 1969.

12. Related Diseases - Related diseases are those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer or stroke.

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IV. GENERAL GRANT INFORMATION

A. Types of Grants

1. Planning - Section 903 of the Act authorizes the Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs, to make grants to assist in the planning and development of Regional Medical Programs.

2. Operational - Section 904 authorizes the Surgeon General, also upon recommendation of the National Advisory Council on Regional Medical Programs, to make grants to assist in the establishment and operation of the Regional Medical Programs. The initial authorization of this program through fiscal year 1968 indicates that operational grants under Section 904 will be considered pilot projects for the establishment and operation of Regional Medical Programs. The designation of operational programs as pilot projects emphasizes the exploratory nature of the first period of authorization.

3. Supplemental - The exploratory and developmental aspects of a Regional Medical Program, both in the planning and operational phases, lead to the expectation that the grantee will wish to add additional

program elements or to expand existing program elements subsequent to the award of the initial grant. The practice of submitting requests for supplemental funds is encouraged insofar as the submission of a supplemental request is preferable to the inclusion in the initial application of program elements which represent only very preliminary ideas or for which it is difficult to justify particular budget requests. Supplemental grant requests will be submitted on the same form as the initial application and will go through a similar review and award process.

B. Relationship of Planning Grant to Operational Grant

The Act does not provide a specific sequential relationship between planning grants under Section 903 and operational grants under Section 904. The operation of a Regional Medical Program obviously should be based upon sound planning. For example, one purpose of planning for a region is to help establish the geographic boundaries that are necessary for effective and efficient operation of the region. Planning also provides an opportunity for the advisory group to participate in the initial stages of the program. In some areas of the country, much relevant planning may have taken place before passage of this legislation. In such instances the grantee may request an operational grant without having first applied for a planning grant under Regional Medical Programs.

A grantee who has received a planning grant need not wait for the completion of that planning grant before applying for an operational grant under Section 904. The grantee may wish to request funds under Section 904 to finance operational activities which represent the first elements of a complete Regional Medical Program. Such grants for the partial implementation of a Regional Medical Program will be awarded, however, on the condition that the planning for implementation of additional phases of the Regional Medical Program will proceed. Grants for partial implementation will be awarded for limited time periods and the continuation of such a grant will be conditioned upon the submission, review, and approval of additional elements of the complete Regional Medical Program by the end of the initial period of award. The purpose of these conditions is to allow initial steps in the implementation of a Regional Medical Program, while at the same time, insuring progress toward the full development of the Regional Medical Program.

Planning should continue after the initiation of an operational program under Section 904. This continued planning may be financed either by continuing the planning grant under Section 903, or by the inclusion of the support of planning activities under the operational grant. Conversely, however, operational activities may not be supported from planning grant funds.

C. Eligible Activities

This section gives examples of types of activities which would be eligible for support under a Regional Medical Program grant. The intent of the program is to encourage innovations and creativity in the development through cooperative efforts of program elements to be included

in the Regional Medical Program. The listing therefore is intended to be helpful in the understanding of the scope of a regional medical program, rather than to be definitive.

Many different types of activities can be supported under a Regional Medical Program grant. Special attention must be given to the functional interrelationships among the various program elements, and how they relate to the goals of the Regional Medical Program.

Certain program elements deserve special discussion. Applications for a Regional Medical Program grant, both planning and operational, must include specific reference to program plans for education and training of health personnel. Continuing education should receive particular emphasis as an integral part of the total Regional Medical Program. However, meritorious programs of continuing education presented in the absence of, or unrelated to, plans for the fuller development of a Regional Medical Program cannot be supported through grants under this program. Therefore, the relationship of continuing education to other aspects of the proposed planning or operational activity must be indicated.

Both the planning and operational phase of a Regional Medical Program should stress the development of more effective relationships between ongoing research activities in the fields of heart disease, cancer, stroke, or related diseases and the other proposed activities of an educational or service nature under the Regional Medical Program. The Regional Medical Program should seek to maintain an effective interaction between ongoing research activities and other aspects of the Regional Medical Program, so as to assure that the activities specifically directed toward the goal of improved diagnosis and treatment may receive the benefits

of future research advances.

1. Under Planning Grant (including Feasibility Studies)

The scope of planning activities which are related to accomplishing the objectives of the Regional Medical Programs can be quite broad. However, planning and conceptualization concerned with general health matters but not related to development of a Regional Medical Program should not be included.

In general, planning should include studies of resources, distribution of services, patient flow, and program elements that are needed, design of specific program elements that includes a mechanism for program evaluation, planning for cooperation among institutions, and planning toward the more effective distribution and utilization of all types of medical resources.

The emphasis on continuing education in the Act deserves particular mention. Creative approaches in the development and management of cooperative arrangements to achieve high quality education programs as well as new ways of applying educational research findings are vital. Indeed the history of the legislation itself stimulates this aspect of regional medical programs.

Examples of activities for consideration in planning in the area of continuing education and training are: identification of existing educational and training programs within the region; evaluation of additional educational and training needs in the region; projections of methods of meeting those needs including specification of appropriate curriculum content, etc.; preliminary thoughts relative to the mechanism of evaluating the effectiveness of future programs in meeting

the needs; the relationship of continuing education and training programs to the overall objectives of the Regional Medical Program including their anticipated effectiveness in bringing about cooperative arrangements between the various health institutions and personnel within the region.

2. Under an Operational Grant - Pilot projects for the establishment and operation of a Regional Medical Program can cover a great variety of activities.

a. Continuing Education and Training - It is assumed that before applying for an operational grant in this area, certain activities will have been undertaken during the planning process (see above). Operational grant funds can support costs of programs including teaching staff, equipment, educational materials, transportation, rental or renovation of space and related demonstrations of patient care. However, the grant may not supplant previous support for ongoing activities in this area. Documentation of the additive nature of the proposed program should be made. Stipends for trainees and participants in the program will be considered only when it is fully documented that such funds are not available from other sources and their expenditure is absolutely necessary for the implementation of the program.

In those instances where major expenditures for equipment and supplies are requested special emphasis should be given to measurement of the effectiveness of the program including measurements in the change in performance of the participants, numbers of participants, and degree to which the information produced might be applicable to other regional medical programs. There should also be acknowledgement of related efforts already accomplished by others with indications of the manner by which the proposed project will

extend those efforts. It is anticipated that such major investments for equipment and supplies will more appropriately be in pilot projects or operational grants rather than in feasibility studies or planning grants.

Considerations under the Regional Medical Programs will be given to continuing education and training programs for medical, allied health personnel and associated professions. However, it should be emphasized that the primary intent of the legislation in this area is the support of those activities that are beyond those normally accepted as basic preparation for work in the health field. Thus, support of basic programs in medical education, residency training, and basic education and training in allied health areas is not normally anticipated. If, however, the applicant can demonstrate that funds are not available from other sources and the particular basic educational program is essential to the success of the Regional Medical Program then consideration will be given to such a request.

Applicants are encouraged to explore innovative training approaches and the development of new types of health personnel to meet the manpower needs of the region as identified in the planning process.

b. Research - Research into better means of accomplishing the purposes and objectives of the Regional Medical Program is supportable under an operational grant. Since other Public Health Service grant mechanisms provide excellent means for the support of biomedical research, the grantee under a Regional Medical Program is required to look to these and other sources of support as well. The support of research activities through other Public Health Service research support mechanisms does not lessen the importance of planning and implementing a Regional Medical Program in a manner which insures a close and continuous linkage

COMMUNICATIONS AND PUBLIC INFORMATION

The development and operation of regional medical programs, individually and collectively, can be aided by well conceived, properly implemented, and continuous communication and public information techniques and activities which are designed to provide a maximum of understanding, participation and support among cooperating organizations and individuals, as well as among lay publics for whom the programs will be established.

To plan and implement such activities, provision for including professional staffing and budgetary support for a communication and public information component may be included in grant applications.

A communication and public information component as an integral part of the proposed regional medical program might include....

- Utilization of a qualified communication and public information specialist, and necessary supporting staff, in both planning and operational activities.

- Development of studies to evaluate professional and public attitudes toward the programs.

- Development and maintenance of a flow of professional and general information to all special and general interest groups and publics, among other existing regional medical programs, and between them and the Division of Regional Medical Programs.

- Preparation and distribution of printed, visual and other informational material for professional and lay publics.

- Participation of this component in planning and conducting programs, seminars, conferences and other means of exchanging professional and general information.

Plans that do not specifically further understanding, participation and support as previously defined, or which would appear to provide only for publicity for the program and aggrandisement of its officials, should not be included.

Questions related to these aspects of a proposed program may be directed to the Division of Regional Medical Programs for answers or special consultation.

investments, they should include (as mentioned under Continuing Education and Training above) documentation of: the measurements of effectiveness of the program; the numbers of people affected by the system; the degree to which the information produced might be generalized to other Regional Medical Programs; and knowledge of related efforts already accomplished by others with indications of the manner by which the proposed project will extend those efforts.

g. Computers - Grant funds may be used to purchase computer time, or if the needs of the program are sufficient, the rental of a computer. As with all other activities, the costs of acquiring computer capability must be measured against the benefits to be derived for the program.

h. Diagnostic and Treatment Equipment - Funds may be used to purchase diagnostic and treatment equipment which is identified, through the planning process, as being a specific need of the region in carrying out the purposes of the program. The location of such equipment should be planned with its efficient and effective use in mind.

i. Support of Staff in Cooperating Institutions - The grant can be used to pay the salary of staff involved in the conduct of the Regional Medical Program, not only in the grantee institution but also in the other institutions cooperating in the program. The level of salary support must be consistent with the salary policies of the institution concerned. The staff might be engaged in supervising and coordinating the activities of the Regional Medical Program in the institution or be involved in specific program elements, such as those discussed above.

j. Consultant Services - The grant could pay for consultant services related to any program element of the Regional Medical Program

and justified as the most effective means of accomplishing a particular purpose to be served.

k. Transportation of Patients - When justified as the most efficient means of carrying out the purpose of the program, grant funds may be used to pay the costs of transportation of patients referred for diagnosis and treatment in other institutions as part of a research, training or demonstration program. The use of grant funds to pay transportation costs should be carefully weighed against the use of funds for other activities within the Regional Medical Program.

D. Relationship to Other Sources of Support

It is expected that no institutional funds formerly devoted to these activities will be displaced by the use of the Regional Medical Program grant. Not only should the grantee avoid substituting these grant funds for other sources of support, but he should also continue to seek additional resources for carrying out the objectives of the Regional Medical Program.

E. Single Grant Approach

Planning as well as operational grants will each be single instruments of support for activities under the Regional Medical Programs. The single grant approach is intended to insure an appropriate degree of cohesiveness in the cooperative approach.

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V. PREPARATION AND REVIEW OF APPLICATIONS

A. Eligible Applicants

The following are eligible applicants for both planning and operational grants: public, or private non-profit universities, medical schools, research institutions, and other public, or non-profit private agencies and institutions located in any state, the District of Columbia, Puerto Rico, or the Virgin Islands. The applicant must be authorized to represent the participating institutions who propose to be involved in the planning and operation of the Regional Medical Program. The applicant must be able to exercise program coordination and fiscal responsibility in assuring the effective use of the grant funds. The applicant is legally responsible for expenditure of funds both by itself and cooperating institutions.

B. Method of Obtaining Application

Application form NIH-925, which is used both for planning and operational grants, whether they are new, continuation, or supplemental, may be obtained by writing the Division of Regional Medical Programs, National Institutes of Health, Bethesda, Maryland, 20014.

C. Method of Preparing Application

Applications should be prepared in accordance with information contained in these guidelines and with the specific instructions included with the application.

D. Review of Application

Applications will be reviewed by the staff, by consultants to the Division of Regional Medical Programs, and as required by statute, by the National Advisory Council on Regional Medical Programs. Under terms of the law, a grant may not be awarded unless it has been recommended for approval by the National Advisory Council.

The rigorous review process requires that sufficient information be provided in the application to enable the reviewers to reach considered and informed judgments concerning the nature, feasibility and soundness of the proposal and to weigh the use of grant funds for the particular proposal against benefits to be gained from the use of grant funds elsewhere.

Time involved

A complete, informative application will facilitate and expedite the review of an application. When necessary in the judgment of the staff or consultants, additional information or justification may be required either by supplemental documents or by conferences and visits.

E. Notification of Applicant

Copies of a Notice of Grant Awarded are sent to the grantee. This notice indicates the program period, the amount being awarded (including the budget period covered), and any special conditions under which the grant is awarded.

F. Financial Management

1. General Requirements - Funds granted may be used only for services, materials and other items required to carry out the approved program. Circular A-21 of the Bureau of the Budget should be used to the extent practicable in determining allowable costs related to the grants for Regional Medical Programs. Where the Division of Regional Medical Programs requires prior approval for items not listed in the approved budget, a written request must be made by the grantee to the Division of Regional Medical Programs in advance of the performance of the act which requires the obligating or expenditure of funds.

2. The Amount Awarded - There is no fixed limitation on the amount of funds that may be awarded. The budget must have a direct relationship to the activities proposed. The size of the various program elements included in the budget should be carefully considered in terms of the relative effectiveness in accomplishing the purposes of the Regional Medical Program. The budget should also have a direct relationship to the reasonable expectations for the rate of implementation of the proposed programs.

3. Direct Costs - The following are examples of direct costs that may be charged to a Regional Medical Program grant:

a. Personnel - Salaries, wages, and fringe benefits of personnel in proportion to the time or effort expended on the program and in accordance with institutional policy, may be charged to this category. Adequate time and effort records must be maintained in order to substantiate these costs.

b. Consultant Costs - Grant funds may be used to pay consultant fees for services related to any program element of the Regional Medical Program providing that these services are the most effective means of accomplishing a particular purpose, and that the consultant is not on the staff of the grantee or cooperating institution.

If consultation is obtained from a staff member of the grantee or cooperating institution, a proportionate amount of his regular salary may be paid by the grant. In either case, consultant costs must be supported by a clear statement of services performed and if appropriate, the number of man days of service.

c. Hospitalization Costs - The method of determining hospitalization costs is still under consideration by the Division of Regional Medical Programs. It will be distributed at a later date.

d. Travel - Per diem reimbursements to travelers, personal transportation charges, and reimbursements for authorized use of personally owned automobiles are chargeable under this category.

Less than first class travel accommodations shall be used except in extenuating circumstances. Automobile mileage and any foreign travel must be in accordance with institution policy. Any foreign travel must receive prior approval from the Division of Regional Medical Programs.

e. Rent - The expenses for rental of facilities not owned by the grantee or participating institution may be charged in proportion to the space actually utilized for the program. Rental costs may not be in excess of comparable rentals in the particular locality, and must be in accordance with institution policy.

f. Communication - That portion of communication charges necessary to the planning or implementation of the program or project may be charged to this category. In no case may institutional local and regular monthly telephone costs and normal postage charges not related to the Regional Medical Programs be charged to the grant.

g. Printing and Reproduction - Printing of pamphlets, brochures and other materials necessary for this program may be charged to this category.

h. Equipment - Rental and purchase of equipment for the planning or implementation of a program may be charged to this category. When acquiring equipment, consideration of the relative advantages of lease versus purchase should be considered.

i. Alteration and Renovation ("Construction") - Under the Act "construction" means alteration, restoration to a sound state, remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete built-in equipment of existing buildings. Built-in equipment is equipment affixed to the facility and customarily included in a building contract. The applicant is required to furnish in sufficient detail plans and specifications, as well as a narrative description, to indicate the need, nature and purpose of the proposed "construction."

Operational grant funds may not support more than 90% of the cost of such "construction" or equipment.

New facilities may not be constructed under this program. Where construction of new facilities is considered necessary for furthering the program, the applicant may seek construction funds under other applicable Federal programs, such as the Hill-Burton, Health Research Facilities, and the Health Professions Educational Assistance programs.

j. Direct Costs not Permitted - The following direct costs or charges are not allowable:

- (1) Honoraria as distinguished from consultant fees
- (2) Entertainment (cost of amusement, social activities, entertainment and incidental costs thereto, such as meals, lodging, rentals, transportation and gratuities)
- (3) Payment to Federal employees
- (4) Petty cash funds
- (5) Subgranting (a subgrant is any allocation of grant funds by the grantee to other individuals or organizations for purposes over which the grantee institution named on the application does not maintain scientific and financial responsibility. A grantee may contract for services, but may not subgrant.)

4. Indirect Costs - Institutional indirect cost rates will be based on the percentage relationship that total institutional indirect cost is to the total direct salaries and wages paid by the institution (not just the research indirect cost pool).

Data taken directly from the grantee or cooperating institutions most recent annual financial report and immediately available supporting information will be utilized as a basis for determining the indirect cost rate applicable to a Regional Medical Program grant at the institution.

Total expenditures as taken from the most recent annual financial report will be adjusted by eliminating from further consideration the following items or categories of expenditure:

a. The costs of equipment, buildings, and repairs which materially increase the value or useful life of buildings or equipment.

However, depreciation and use charges may be included in determining total expenditure.

b. Advertising other than for recruitment of personnel, procurement of scarce items or the disposal of scrap or surplus material.

c. Bad debts

d. Contingency reserves

e. Commencement and convocation costs

f. Entertainment costs

g. Fines and penalties

h. Interest, fund raising and investment management costs

i. Losses on other agreements or contracts

j. Profits and losses on disposition of plant, equipment, or other capital costs.

- k. Public information services costs
- l. Scholarships and student aid costs
- m. Special services costs incurred for general public relations
- n. Student activity costs
- o. Student dormitory costs
- p. Student services costs
- q. Costs used in arriving at a hospitalization rate or interdepartmental charge
- r. Unrelated hospital costs
- s. Other inappropriate costs

Where any types of expense ordinarily treated as general administration and general expenses or departmental administration expenses are charged to a Division of Regional Medical Programs grant as direct costs, the similar type of expenses applicable to other activities of the institution must, through separate cost groupings, be excluded from the indirect costs allowable to a Division of Regional Medical Programs grant.

The indirect cost rate will then be computed by dividing the total direct salaries and wages paid by the institution into the total adjusted indirect cost incurred by the institution.

When, under an operational grant, the cooperating institutions are preparing their budgets for submission to the grantee, the institutions' indirect cost rates, based on salaries and wages, should be stated in the budget. To substantiate this rate, the cooperating

institutions should supply the grantee with adequate substantiating data, such as documents certifying that the overall institutional indirect cost rate has been audited and approved by the PHS, another Government agency, or an independent accounting firm. In addition, the total institutional indirect cost, and direct salaries and wages should be stated as separate amounts. The institution should indicate whether fringe benefits are included in the salary and wage base or not. A detailed indirect cost proposal should accompany each new or continuing grant application. When an applicant is submitting a planning grant application to the Division of Regional Medical Programs, the above procedures also apply.

Indirect costs are those which, because of their incurrence usually for common or joint objectives, are not readily identified with individual projects. All costs representing charges associated with the activities of the grantee or cooperating institutions which are supportive of the conduct of the Regional Medical Program, except those which are specifically approved by the Division of Regional Medical Programs as direct costs, are classified as indirect costs. The general types of indirect costs are:

- a. General administration and expenses which are incurred for the executive and administrative offices of an institution receiving grants, and other expenses of a general character which do not relate solely to any specific unit in the institution, or to any specific project in the institution;

b. Program administration expenses which apply to program activities administered in whole or in part by a separate organization or an identifiable administrative unit. Examples of work relating to grant programs which is sometimes performed under such organizational arrangement are: grant administration, purchasing, personnel, accounting, etc.;

c. Operation and maintenance expenses incurred for operating and maintaining an institution's physical plant, including expenses normally incurred for administration or supervision of the physical plant; janitorial service; utilities, including telephone installation and maintenance costs; and other expenses customarily associated with the operation, maintenance, preservation, and protection of the institution's physical facilities;

d. Reimbursements and other receipts from the Federal Government which are used by the institution to support directly, in whole or in part, any of the administrative or service (indirect) activities received pursuant to an institution's base grant or any similar contractual arrangement with the Federal Government shall be treated as a credit to the total indirect cost pool. Such set-off shall be made prior to the determination of the indirect cost rate submitted to the Division of Regional Medical Programs. These credits include indirect cost reimbursements

contained in payments for hospitalization, interdepartmental charges and centralized facilities operated by the institution.

5. Rebudgeting of Funds - The grantee or cooperating institutions may depart from the approved budget and use the funds for other items required for the project, except for the following restrictions:

- a. Grant funds may not be used for any purpose contrary to the regulations and policies of the Division of Regional Medical Programs or the grantee or the cooperating institutions.
- b. Grant funds may be transferred between budget categories to the extent that no category is increased or decreased by more than 20% of the approved budget. Increases or decreases in a budget category in excess of 20% must be approved by the Division of Regional Medical Programs.

6. Refunds - During the program period, refunds and rebates should be credited to the account. Credits received after the termination of the program period shall be returned to the Public Health Service. Checks should be made payable to National Institutes of Health, PHS, DHEW, Bethesda, Maryland, 20014.

- a. Interest and other income - Interest or other income earned on grant funds must be returned to the Public Health Service.

- b. Royalties and Profits - When the costs of publishing material are provided from Public Health Service grants, any royalties or profits up to the amount charged to the grant for publishing the material shall be refunded to the Public Health Service.

✓ 7. Unexpended Balance - Continued use of any unobligated or unexpended funds remaining in the grant account at the end of the budget period should be justified by the grantee when the Expenditures Report is submitted to the Division of Regional Medical Programs. If adequate justification is received, the Division of Regional Medical Programs will advise the grantee that such funds may be used during the subsequent budget period. If inadequate justification, or no justification is presented, unexpended funds will be used toward payment of the total amount requested for the subsequent budget period. The unexpended balance as shown in the final Expenditures Report must be returned to the National Institutes of Health, PHS, DHEW, Bethesda, Maryland, 20014.

8. Obligations or Expenditures - Obligations, commitments, encumbrances, or expenditures will normally be made within the period indicated on the notice of grant award. Grant funds may not be used to reimburse any such obligations, commitments or expenditures made prior to the beginning date of the initial grant for a new or renewal project. In exceptional instances the grantee may, at its own risk, prior to the

beginning date of a continuation award, incur expenditures which exceed existing Division of Regional Medical Programs authorization but which are considered essential to the conduct of the project. The Division of Regional Medical Programs may allow reimbursement of such expenditures from the continuation grant.

9. Accounting Records and Audit -

a. Accounting - Accounting for grant funds will be in accordance with the grantee and/or cooperating institution accounting practices consistently applied regardless of the source of funds. Itemization of all supporting expenditures must be recorded in sufficient detail to show the exact nature of expenditures. Each recipient of grant funds shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the program or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the program or undertaking supplied by other sources, and to make such records available as will facilitate an effective audit by authorized personnel. Such a system must meet the following criteria:

- (1) A special grant account must be established for each Regional Medical Program grant and be maintained at the grantee institution designated on the application.

Responsibility for expenditure of funds by participating institutions must be assumed by the named grantee institution.

- (2) The accounting records at the grantee institution shall provide the information needed to identify the receipt and expenditure of all program funds separately for each grant. Expenditures shall be recorded by the component program and budget cost categories shown in the approved budget.
- (3) Each entry in the accounting records at the grantee or cooperating institution shall refer to the documentation which supports the entry and the documentation shall be filed in such a way that it can be readily located.
- (4) The accounting records shall provide accurate and current financial reporting information.
- (5) The accounting system shall possess an adequate means of internal control to safeguard the assets, check the accuracy and reliability of the accounting data, promote operational efficiency, and encourage adherence to prescribed management policies.

b. Records - The financial records, including all documents to support entries on the accounting records, must be kept readily available for examination by authorized personnel.

No such records shall be destroyed or otherwise disposed of within three years after the termination of the program. Unless written approval is obtained from the Public Health Service to dispose of the records, they must be retained until the audit has been completed and all questions about the expenditures are resolved.

c. Audit - The Division of Regional Medical Programs follows generally accepted auditing practices in determining that there is a proper accounting in use of grant funds. Failure of a grantee to appeal a proposed audit disallowance within thirty days after receipt of a written notification will make the action of the Division of Regional Medical Programs conclusive.

10. Equipment (Title and Accountability)

Title to equipment purchased with grant funds resides in the grantee institution and accountability may be waived at the termination of the grant by the Division of Regional Medical Programs as long as the equipment is used to further the objectives of the Public Health Service. The Division of Regional Medical Programs, however, reserves the right under unusual circumstances to transfer title of equipment to the Division of Regional Medical Programs or to another grantee.

Excess materials and supplies retained by the grantee upon termination of the program may be accounted for under the same terms as equipment.

G. Additional Funds

To obtain additional funds for support of a program, the procedures vary according to the need as follows:

1. For continued support - An application form requesting support for the next budget period of the program period (continuation grant) will be mailed to the grantee institution about 4 months before the beginning date of the next budget period. It is the responsibility of the grantee to request this application form if it is not received. The application should be submitted in accordance with the instructions accompanying the form.
2. For supplemental funds - If additional funds to conduct the program are required within any portion of the program period over those budgeted and approved, and such funds are not available within the institution receiving support for the program, a supplemental application may be submitted. A face sheet, budget page, and justification are required for a supplemental award. A supplemental grant forms a part of the initial award and only one report of expenditures is required.

Supplemental applications are processed in the same manner as new applications and must compete for available funds, except those applications to meet increased administrative costs, such as fringe benefits or salary increases, may be administratively approved.

3. Support beyond the Program Period - If additional support beyond the program period is required, a new application must be submitted. This application will go through the normal review process and will compete with other applications for available funds. If approved, an initial grant for a new program period will be awarded.

H. Program Evaluation

The grantee should make a special effort to incorporate into all aspects of the planning and operational activities appropriate mechanisms for evaluating the effectiveness of all aspects of the Regional Medical Program. The concern with the evaluation should begin in the planning process so that the planning process may include planning for evaluation mechanisms. The exploratory nature of the Regional Medical Programs makes the need for the realistic evaluation mechanisms especially important. Particular attention to the evaluation process will provide the means for the grantee to assess his progress and accomplishments and will also provide the basis for the preparation of progress reports which can be used by the Division of Regional Medical Programs in evaluating the accomplishments of the total national program.

I. Changes in Approved Program

The Division of Regional Medical Programs does not intend to interfere with administrative or program flexibility which serves the objectives of the Regional Medical Programs. If, however, a change is determined by the grantee to be desirable, and if that change would constitute a substantial change in the nature of the program originally approved, the grantee should consult with the Division of Regional Medical Programs staff.

J. Change of Grantee

If the grantee expects to relinquish active direction of the program, the Division of Regional Medical Programs must be notified immediately. The grantee may request that the grant be terminated, in which case a terminal progress report, an expenditures report, and invention statement (PHS-3945) must be submitted. The grantee may request that the program be continued under the direction of another institution.

If the grantee terminates its responsibility for the program, the new institution may submit a new grant application for the remainder of the program period. The application should include the reasons for transferring the program and the probable effect of the move on the program. Administrative approval may be given by the Division of Regional Medical Programs to continue the program at the new institution. Applications, however, that reflect major changes will be referred to the National Advisory Council on Regional Medical Programs for recommendation.

K. Change of Program Coordinator

The program coordinator named in the application shall be responsible for coordination of the program during the period for which the grant was awarded.

A change of program coordinator or other key official directing the program requires approval by the Division of Regional Medical Programs. The grantee is required to notify the Division of Regional Medical Programs if such a change is necessary.

L. Change in Program Period

The program period may be extended up to 12 months ~~(but not beyond June 30, 1969)~~ without additional funds, if requested by the grantee before the end of the program period.

M. Early Termination of Grant

1. By the Grantee - A grant may be terminated or cancelled at any time by the grantee upon written notification to the Division of Regional Medical Programs stating the reasons for termination.

2. By the Public Health Service - A grant may be revoked or terminated by the Surgeon General, in whole or in part, in any time within the program period whenever it is determined that the grantee has failed in a material respect to comply with the terms and conditions of the grant. The grantee will be promptly advised of the reasons for termination of the grant in writing.

N. Reports

All reports required to be submitted to the Public Health Service should be sent to the Division of Regional Medical Programs, Public Health Service, Bethesda, Maryland, 20014.

1. Progress Reports - The grantee is required to submit an annual progress report. This report should contain sufficient detail to inform the reader of the accomplishments with particular respect to the objectives originally set forth. These progress reports must

be submitted with the application for a continued support. In addition, grantees may be required to supply other information needed for guidance and development of the national program and are encouraged to report significant developments promptly at any time. A terminal progress report must be submitted to the Division of Regional Medical Programs within three months of the termination of the program period.

2. Regional Advisory Group - The Regional Advisory Group is expected to prepare an annual statement on the effectiveness of the regional cooperative arrangements established under the Regional Medical Program. The report should be submitted to the Division of Regional Medical Programs by the grantee along with the annual progress report. Periodic reviews of grants by the staff of the Division and the Advisory Council will include consideration of the effectiveness of the Advisory Group in serving its essential purpose.

3. Expenditures Report (Form NIH-925-3) - A single expenditures report and a single narrative progress report is required to be submitted by the named grantee on behalf of all cooperating institutions to the Division of Regional Medical Programs for each budget period of the program period. If the grantee fails to submit an expenditures report within 120 days after the end of each budget period, future awards for that project may be withheld.

A supplemental grant forms a part of the existing grant and only one expenditure report need be submitted on the combined grants.

4. Time or Effort Report - Charges for salaries and wages of individuals other than members of the professional staff will be supported by time and attendance and payroll distribution records. For members of the professional staff, quarterly estimates of the percentage distribution of their total effort must be used as support in the absence of actual time records. Time and effort reports are not to be sent to the Division of Regional Medical Programs but must be retained by the grantee and must be made available for inspection by the Public Health Service staff.

5. Invention Report - Immediate and full reporting of all inventions to the Public Health Service is required.

0. Miscellaneous

1. Safety Precautions - The Public Health Service assumes no responsibility with respect to accident, claims or illness arising out of any work undertaken with the assistance of a Public Health Service grant. The grantee institution is expected to take necessary steps to insure or protect itself and its personnel.

2. Federal Income Tax - Determination of a tax status of an individual receiving compensation in any form from the Public Health Service grant is the responsibility of the Internal Revenue Service.

3. Military Service - The Public Health Service will not intercede on behalf of an individual in relation to military status.

EXHIBIT



Public Law 89-239
89th Congress, S. 596
October 6, 1965

An Act

79 STAT. 926

To amend the Public Health Service Act to assist in combating heart disease, cancer, stroke, and related diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Heart Disease, Cancer, and Stroke Amendments of 1965".

SEC. 2. The Public Health Service Act (42 U.S.C., ch. 6A) is amended by adding at the end thereof the following new title:

Heart Disease,
Cancer, and
Stroke Amend-
ments of 1965.
58 Stat. 682.
42 USC 201 note.

**"TITLE IX—EDUCATION, RESEARCH, TRAINING, AND
DEMONSTRATIONS IN THE FIELDS OF HEART DIS-
EASE, CANCER, STROKE, AND RELATED DISEASES**

"PURPOSES

"SEC. 900. The purposes of this title are—

"(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases;

"(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

"(c) By these means, to improve generally the health manpower and facilities available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies.

"AUTHORIZATION OF APPROPRIATIONS

"SEC. 901. (a) There are authorized to be appropriated \$50,000,000 for the fiscal year ending June 30, 1966, \$90,000,000 for the fiscal year ending June 30, 1967, and \$200,000,000 for the fiscal year ending June 30, 1968, for grants to assist public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private institutions and agencies in planning, in conducting feasibility studies, and in operating pilot projects for the establishment, of regional medical programs of research, training, and demonstration activities for carrying out the purposes of this title. Sums appropriated under this section for any fiscal year shall remain available for making such grants until the end of the fiscal year following the fiscal year for which the appropriation is made.

"(b) A grant under this title shall be for part or all of the cost of the planning or other activities with respect to which the application is made, except that any such grant with respect to construction of, or provision of built-in (as determined in accordance with regulations) equipment for, any facility may not exceed 90 per centum of the cost of such construction or equipment.

"(c) Funds appropriated pursuant to this title shall not be available to pay the cost of hospital, medical, or other care of patients

except to the extent it is, as determined in accordance with regulations, incident to those research, training, or demonstration activities which are encompassed by the purposes of this title. No patient shall be furnished hospital, medical, or other care at any facility incident to research, training, or demonstration activities carried out with funds appropriated pursuant to this title, unless he has been referred to such facility by a practicing physician.

"DEFINITIONS

"SEC. 902. For the purposes of this title—

"(a) The term 'regional medical program' means a cooperative arrangement among a group of public or nonprofit private institutions or agencies engaged in research, training, diagnosis, and treatment relating to heart disease, cancer, or stroke, and, at the option of the applicant, related disease or diseases; but only if such group—

"(1) is situated within a geographic area, composed of any part or parts of any one or more States, which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of this title;

"(2) consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and

"(3) has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for effectively carrying out the purposes of this title.

"(b) The term 'medical center' means a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.

"(c) The term 'clinical research center' means an institution (or part of an institution) the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients.

"(d) The term 'hospital' means a hospital as defined in section 625(c) or other health facility in which local capability for diagnosis and treatment is supported and augmented by the program established under this title.

"(e) The term 'nonprofit' as applied to any institution or agency means an institution or agency which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"(f) The term 'construction' includes alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

"GRANTS FOR PLANNING

"SEC. 903. (a) The Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs established by section 905 (hereafter in this title referred to as the 'Council'), is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist them in planning the development of regional medical programs.

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"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it contains or is supported by—

"(1) reasonable assurances that Federal funds paid pursuant to any such grant will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder;

"(2) reasonable assurances that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) reasonable assurances that the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) a satisfactory showing that the applicant has designated an advisory group, to advise the applicant (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan for the establishment and operation of such regional medical program, which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the need for the services provided under the program.

"GRANTS FOR ESTABLISHMENT AND OPERATION OF REGIONAL MEDICAL PROGRAMS

"Sec. 904. (a) The Surgeon General, upon the recommendation of the Council, is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist in establishment and operation of regional medical programs, including construction and equipment of facilities in connection therewith.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it is recommended by the advisory group described in section 903(b) (4) and contains or is supported by reasonable assurances that—

"(1) Federal funds paid pursuant to any such grant (A) will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder, and (B) will not supplant funds that are otherwise available for establishment or operation of the regional medical program with respect to which the grant is made;

"(2) the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

"(3) the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and

Records.

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afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a-276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

49 Stat. 1011;
78 Stat. 238.

64 Stat. 1267.
63 Stat. 108.

"NATIONAL ADVISORY COUNCIL ON REGIONAL MEDICAL PROGRAMS

Appointment of
members.

"SEC. 905. (a) The Surgeon General, with the approval of the Secretary, may appoint, without regard to the civil service laws, a National Advisory Council on Regional Medical Programs. The Council shall consist of the Surgeon General, who shall be the chairman, and twelve members, not otherwise in the regular full-time employ of the United States, who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. At least two of the appointed members shall be practicing physicians, one shall be outstanding in the study, diagnosis, or treatment of heart disease, one shall be outstanding in the study, diagnosis, or treatment of cancer, and one shall be outstanding in the study, diagnosis, or treatment of stroke.

Term of office.

"(b) Each appointed member of the Council shall hold office for a term of four years, except that any member appointed to fill a vacancy prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term, and except that the terms of office of the members first taking office shall expire, as designated by the Surgeon General at the time of appointment, four at the end of the first year, four at the end of the second year, and four at the end of the third year after the date of appointment. An appointed member shall not be eligible to serve continuously for more than two terms.

Compensation.

"(c) Appointed members of the Council, while attending meetings or conferences thereof or otherwise serving on business of the Council, shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding \$100 per day, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

60 Stat. 808;
75 Stat. 339, 340.

Applications for
grants, recommendations.

"(d) The Council shall advise and assist the Surgeon General in the preparation of regulations for, and as to policy matters arising with respect to, the administration of this title. The Council shall consider all applications for grants under this title and shall make recommendations to the Surgeon General with respect to approval of applications for and the amounts of grants under this title.

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"REGULATIONS

"SEC. 906. The Surgeon General, after consultation with the Council, shall prescribe general regulations covering the terms and conditions for approving applications for grants under this title and the coordination of programs assisted under this title with programs for training, research, and demonstrations relating to the same diseases assisted or authorized under other titles of this Act or other Acts of Congress.

"INFORMATION ON SPECIAL TREATMENT AND TRAINING CENTERS

"SEC. 907. The Surgeon General shall establish, and maintain on a current basis, a list or lists of facilities in the United States equipped and staffed to provide the most advanced methods and techniques in the diagnosis and treatment of heart disease, cancer, or stroke, together with such related information, including the availability of advanced specialty training in such facilities, as he deems useful, and shall make such list or lists and related information readily available to licensed practitioners and other persons requiring such information. To the end of making such list or lists and other information most useful, the Surgeon General shall from time to time consult with interested national professional organizations.

"REPORT

"SEC. 908. On or before June 30, 1967, the Surgeon General, after consultation with the Council, shall submit to the Secretary for transmission to the President and then to the Congress, a report of the activities under this title together with (1) a statement of the relationship between Federal financing and financing from other sources of the activities undertaken pursuant to this title, (2) an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title, and (3) recommendations with respect to extension or modification of this title in the light thereof.

"RECORDS AND AUDIT

"SEC. 909. (a) Each recipient of a grant under this title shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such records as will facilitate an effective audit.

"(b) The Secretary of Health, Education, and Welfare and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of any grant under this title which are pertinent to any such grant."

SEC. 3. (a) Section 1 of the Public Health Service Act is amended to read as follows:

"SECTION 1. Titles I to IX, inclusive, of this Act may be cited as the 'Public Health Service Act'."

Report to
President and
Congress.

58 Stat. 682.

42 USC 201-
298b.

79 STAT. 931

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42 USC 201
note.

(b) The Act of July 1, 1944 (58 Stat. 682), as amended, is further amended by renumbering title IX (as in effect prior to the enactment of this Act) as title X, and by renumbering sections 901 through 914 (as in effect prior to the enactment of this Act), and references thereto, as sections 1001 through 1014, respectively.

Approved October 6, 1965, 10:15 a.m.

LEGISLATIVE HISTORY:

HOUSE REPORT No. 963 accompanying H. R. 3140 (Comm. on Interstate & Foreign Commerce).

SENATE REPORT No. 368 (Comm. on Labor & Public Welfare).

CONGRESSIONAL RECORD, Vol. 111 (1965):

June 25: Considered in Senate.

June 28: Considered and passed Senate.

Sept. 23: H. R. 3140 considered in House.

Sept. 24: Considered and passed House, amended, in lieu of H. R. 3140.

Sept. 29: Senate concurred in House amendments.